K130076

510(k) Summary

Merz Dental GmbH Denture Base Resins with Prosthetic Color System

Submitter

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AUG 2 2 2013

Date of Summary: July 17, 2013

Device Name

Proprietary name:	Promolux, Promolux Hi, Weropress, PremEco PCS
Common name:	Denture Base Resin
Classification name:	Resin, Denture, Relining, Repairing, Rebasing (21CFR 872.3760 Product Code EBI)
Predicate Device:	Vertex hot-curing denture base material (K102654) Vertex cold-curing denture base material (K102640)

Device Description:

Merz Dental Denture Base Resins with Prosthetic Color System are composed of the following products:

• Promolux	A heat processed PMMA denture base resin
• Promolux Hi	A heat-processed PMMA denture base resin formulated for greater strength
• Weropress	A two part cold curing PMMA denture base resin
• PremEco PCS	A two part cold curing PMMA denture base resin with individual tints for aesthetic coloration of gingival portion of a denture base

These products are intended for the preparation of denture bases. They are composed of PMMA and cured by standard heat or cold setting methods. The Prosthetic Color System

is a three part system composed of the following: (1) PMMA polymer with various tints in a powder form, (2) MMA liquid for mixing with the powder, and (3) a cold-casting resin (PMMA and MMA) for final preparation of the denture base. The hot and cold curing denture materials contain standard dental colorants and catalyst systems. One of the hot cured dental base materials, Promolux Hi, is formulated to increase impact resistance.

Intended Use

The Merz Dental GmbH Denture Base Resins and Prosthetic Color System are for use in:

- Relining a denture surface that contacts tissue
- Repairing a fractured denture, or
- Forming a new denture base

Technological characteristics and substantial equivalence

The technological characteristics of the Merz Dental GmbH Denture Base Resins with Prosthetic Color System, and those of the predicate devices, are shown in Tables 1 and 2.

The Merz Dental GmbH Denture Base Resins and the predicate devices are composed of the same acrylic material (PMMA), utilize the same curing methods (heat or cold cured), and have similar physical properties. They also have the same indications for use (fabrication of denture bases). They differ with regard to impact resistance (Promolux Hi has a higher impact resistance than the heat-cured predicate). The Merz Dental GmbH Prostheic Color System also adds flexibility in the technician's ability to vary the coloring of the gingival portion of the denture base.

Table 1: Comparison of Promolux and Promolux Hi to the Predicate Vertex Rapid Simplified

Device Heat-Cured	Vertex Rapid Simplified	Promolux	Promolux Hi
Technology	PMMA Acrylic Plastic	PMMA Acrylic Plastic	PMMA Acrylic Plastic
Features	Heat curable	Heat curable	Heat curable
Materials	Two part mix of polymethylmethacrylate powder and methacrylate monomer liquid	Two part mix of polymethylmethacrylate powder and methacrylate monomer liquid	Two part mix of polymethylmethacrylate powder and methacrylate monomer liquid
Operations	Mixed into dough and pressed into flask	Mixed into dough and pressed into flask	Mixed into dough and pressed into flask
Indications	• Relining a denture surface that contacts tissue • Repairing a fractured denture, or • Forming a new denture base	• Relining a denture surface that contacts tissue • Repairing a fractured denture, or • Forming a new denture base	• Relining a denture surface that contacts tissue • Repairing a fractured denture, or • Forming a new denture base
Physical Properties	Impact-resistance Flexural strength Flexural modulus Water sorption Solubility	Impact-resistance Flexural strength Flexural modulus Water sorption Solubility	Impact-resistance Flexural strength Flexural modulus Water sorption Solubility
Bio-compatibility	Composed of biocompatible PMMA with colorants.	Composed of biocompatible PMMA with colorants.	Composed of biocompatible PMMA with colorants.

Table 2: Comparison of Weropress and PremEco PCS to Vertex Castavaria

Device Cold -Cured	Vertex Castavaria	Weropress	PremEco PCS
Technology	PMMA Acrylic plastic	PMMA Acrylic plastic	PMMA Acrylic plastic
Features	Cold Curing	PMMA Acrylic plastic	PMMA Acrylic plastic
Materials	Two part mix of polymethylmethacrylate powder and methacrylate monomer liquid	Two part mix of polymethylmethacrylate powder and methacrylate monomer liquid	Two part mix of polymethylmethacrylate powder and methacrylate monomer liquid
Operations	Mixed dough and pressed into flask	Mixed dough and pressed into flask	Mix powder and liquid and brush on
Indications	• Relining a denture surface that contacts tissue • Repairing a fractured denture, • Forming a new denture base	• Relining a denture surface that contacts tissue • Repairing a fractured denture, • Forming a new denture base	• Relining a denture surface that contacts tissue • Repairing a fractured denture, • Forming a new denture base
Physical Properties	Impact-resistance Flexural strength Flexural modulus Water Solubility	Impact-resistance Flexural strength Flexural modulus Water Solubility	Impact-resistance Flexural strength Flexural modulus Water Solubility
Bio-compatibility	Composed of biocompatible PMMA with colorants.	Composed of biocompatible PMMA with colorants.	Composed of biocompatible PMMA with colorants.

Performance Testing

Tests of the cured polymer base materials was performed according to ISO 1567:2000 "Dentistry – Base polymers – Part 1: Denture base polymers" (for cold curing--Type II: Class 1), and ISO 20795- (for hot curing—Type II, Class 2) The materials met the physical and residual methyl methacrylate monomer requirements.

These well known denture base materials were tested and found to comply with *in vitro* cytotoxicity (ISO 10993-5), guinea pig sensitization (ISO 10993-10.2), physical properties (ISO 1567:2000 for cold-curing polymers; and ISO 20795-1 for hot-curing polymers), and residual monomer requirements. These materials have a long history of safe use and have been extensively tested for physical and biological properties.

Conclusions:

Merz Dental GmbH denture base resins (Promolux, Promolux Hi, Weropress and PremEco PCS) have similar technological and performance characteristics as the currently marketed predicate denture base resins (Vertex Rapid Simplified and Vertex Castavaria). The products are composed of the same biocompatible acrylic plastic (PMMA), utilize the same preparation and casting techniques, and have identical indications for use. Their physical properties are similar for each type of curing system (hot or cold) with the exception that the hot-curing Merz Dental Promolux Hi has a higher impact resistance than the hot-curing Vertex Rapid Simplified. In addition, the Merz Dental PremEco PCS product allows greater flexibility in the coloring of the gingival portion of the denture than the predicate device. Based on the above similarities and differences, it is concluded that the Merz Dental GmbH denture base resin products (Promolux, Promolux Hi, Weropress and PremEco PCS) are substantially equivalent to the predicate denture base resin products (Vertex Rapid Simplified and Vertex Castavaria).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

August 22, 2013

Merz Dental GmbH
C/O Richard G. Hunter, M.S., RAC
Principal
Washington Regulatory Consultants
5616 Mariola Place NE
ALBUQUERQUE, New Mexico 87111

Re: K130076
Trade/Device Name: Merz Denture Base Resins with Prosthetic Color System
Regulation Number: 21 CFR 872.3760
Regulation Name: Resin Denture, Relining, Repairing, Rebasing
Regulatory Class: II
Product Code: EBI
Dated: July 17, 2013
Received: July 18, 2013

Dear Mr. Hunter:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mary S. Runner -S

Kwame Ulmer M.S.
Acting Division Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4. Indications for Use

510(k) Number (if known): K130076

Device Name: Merz Denture Base Resins with Prosthetic Color System

Indications for Use:

The Merz Dental GmbH Denture Base Resins with Prosthetic Color System (Promolux, Promolux Hi, Weropress and PremEco PCS) are indicated for:

- Relining a denture surface that contacts tissue
- Repairing a fractured denture, or
- Forming a new denture base

Prescription Use ___X___ AND/OR Over-The-Counter Use

(21 CFR Part 801 Subpart D) (21 CFR Part 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Andrew I. Steen -S
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(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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